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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,918	12/13/2005	John E. Hansen	13323-105003	5673

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EXAMINER
HAND, MELANIE JO

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
01/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/538,918	HANSEN ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1.88.91-95.97-106.118-120.130-136.138-141.143-158 and 160-164* is/are pending in the application.

4a) Of the above claim(s) *130-136,143,144 and 146-157* is/are withdrawn from consideration.

5)☒ Claim(s) *95,141 and 158* is/are allowed.

6)☒ Claim(s) *1.88.91-94.96-106.118-120.138-140.142.145 and 160-164* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 88, 91-94, 96-106, 118-120, 138-140, 142 and 160-164 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's submission of an information disclosure statement. Claims 95, 141 and 158 are examined herein on the merits. The status of Claim 145 is "withdrawn" in response to applicant's status request and should have been listed with the withdrawn claims in the Office Action Summary form. That error is corrected in this action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on October 13, 2009 was filed after the mailing date of the non-final action on May 14, 2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Alessio in view of Choi (see 892 form attached for full citation).

With respect to **claim 1:** D'Alessio discloses a single-use device. The device is considered herein to be fully functional for sampling or collecting inasmuch as the foam swab 50 is fully capable of collecting tissue cells in the same way that it collects composition thereon to administer to a tissue site. The device comprises a sterile swab 50 inasmuch as the swab is protected by packaging prior to use, and a handle 20 attached to said swab and is contained in a sealed package. (Col. 4, lines 53-64, Col. 6, line 66 – Col. 7, line 8)

D'Alessio discloses that swab 50 is a very soft biocompatible material so that biomedically useful compositions can be applied. (Col. 6, lines 62-65) However D'Alessio does not explicitly disclose that the swab is a gelatin-based sponge. Choi discloses gelatin-based sponges that show good wound-healing performance and that are capable of administering drugs to a healing wound, e.g. a stomatitis lesion as disclosed by D'Alessio. Therefore it would eb obvious to one of ordinary skill in the art to modify the swab disclosed by D'Alessio so as to comprise a gelatin-based sponge as disclosed by Choi to provide a material that is biocompatible and capable of administering healing drugs to treat the lesion. (Choi, Page 72, 2nd col.)

With respect to **claim 88:** D'Alessio does not explicitly disclose that the swab is a gelatin-based sponge. Choi discloses a gelatine-based sponge having a water absorption capacity of either 31.8-42.2 g/g, which overlaps the claimed range of at least 30 g/g. (Choi, Table 1, GH and GA samples) The motivation to modify the swab of D'Alessio so as to comprise a gelatin-based sponge is stated *supra* with respect to claim 1. With regard to the limitation "as determined by USP method "Absorbable Gelatin Sponge: Water Absorption", the test method recited in the claim *per se* does not substantially affect the value of a specific parameter, which is a characteristic of the material and depends on the structure and make up of a material, but not on the method of its determination. Since the test method does not essentially affect the composition of the gelatine swab material of D'Alessio as modified by Choi during testing, the test method bears little patentable weight because any test method will yield substantially identical results, and thus the test method used cannot be the basis for patentability over the prior art.

6. Claims 91-95, 97-99, 101, 103, 105, 106, 118-120, 138-140, 161, 163 and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Choi et al (see PTO-892 for full citation).

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With respect to **claim 91:** Kelly discloses a kit comprising the following: i) a swab and a handle attached to said swab; and ii) an agent in the form of Stuart Transport Medium, which is considered herein to be a neutral diluent inasmuch as its final pH is 7.4±0.2 (see attached reference material for Stuart Transport Medium).

With further regard to item i), Kelly discloses Gelfoam, which may be construed by one of ordinary skill in the art to be a gelatine-based sponge at the time of the Kelly reference (see

attached Gelfoam trademark dated prior to the Kelly reference). However Kelly does not explicitly disclose a gelatine-based sponge. Choi discloses gelatin-based sponges that show good wound-healing performance and that are capable of administering drugs to a healing wound such as that disclosed by Kelly. Therefore it would be obvious to one of ordinary skill in the art to modify the swab disclosed by Kelly so as to comprise a gelatin-based sponge as disclosed by Choi to provide a material that is biocompatible and capable of administering healing drugs to treat the lesion. (Choi, Page 72, 2nd col.)

With respect to **claim 92:** The neutral diluent disclosed by Kelly is Stuart Transport Medium, which is an organic buffer.

With respect to **claim 93:** Kelly discloses a method for collecting a target from a collection medium, namely a wound environment, comprising the following steps: i) providing a swab; and ii) making contact between the swab and the target, i.e. bacteria in the wound, to transfer said target from the collection medium to the swab; and iii) transferring said target from the swab to a transfer medium, i.e. Stuart's transport medium, to thereby recover said target from said collection medium.

With further regard to item i), Kelly discloses Gelfoam, which may be construed by one of ordinary skill in the art to be a gelatine-based sponge at the time of the Kelly reference (see attached Gelfoam trademark dated prior to the Kelly reference). However Kelly does not explicitly disclose a gelatine-based sponge. Choi discloses gelatin-based sponges that show good wound-healing performance and that are capable of administering drugs to a healing wound such as that disclosed by Kelly. Therefore it would be obvious to one of ordinary skill in the art to modify the swab disclosed by Kelly so as to comprise a gelatin-based sponge as

disclosed by Choi to provide a material that is biocompatible and capable of administering healing drugs to treat the lesion. (Choi, Page 72, 2nd col.)

With respect to **claim 94:** The swab comprises a gelatin-based sponge inasmuch as it comprises a Gelfoam swab, which is by its nature a gelatin-based sponge.

With respect to **claim 97:** Kelly discloses a method of lowering the amount of a target, i.e. bacteria, in a sample area, i.e. a wound comprising the following steps: (i) making contact between a swab and at least a portion of said sample area, so that an amount of the target adheres to the swab, defining the bacteriological swabs disclosed by Kelly, and (ii) transferring the adhered target from the swab to a transfer medium, namely Stuart transport medium.
a Gelfoam swab comprising gelatin

With further regard to item i), Kelly discloses Gelfoam, which may be construed by one of ordinary skill in the art to be a gelatine-based sponge at the time of the Kelly reference (see attached Gelfoam trademark dated prior to the Kelly reference). However Kelly does not explicitly disclose a gelatine-based sponge. Choi discloses gelatin-based sponges that show good wound-healing performance and that are capable of administering drugs to a healing wound such as that disclosed by Kelly. Therefore it would be obvious to one of ordinary skill in the art to modify the swab disclosed by Kelly so as to comprise a gelatin-based sponge as disclosed by Choi to provide a material that is biocompatible and capable of administering healing drugs to treat the lesion. (Choi, Page 72, 2nd col.)

With respect to **claim 98:** The collection medium disclosed by Kelly is a wound surface, i.e. combination of a solid surface, a semi-solid surface, and a liquid.

With respect to **claim 99:** The target disclosed by Kelly is a microorganism, i.e. bacteria.

With respect to **claim 101:** Kelly discloses the transfer of bacteria onto the swab, wherein bacteria exhibit enzymatic activity in a wound environment and on the swab, producing enzymes that digest gelatin. However Kelly does not explicitly disclose a gelatine-based sponge. Choi discloses gelatin-based sponges. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93. Thus, it is examiner's position that the transferring step disclosed by Kelly as modified by Choi necessarily includes digestion of said gelatin.

With respect to **claim 103:** The digestion in the method of Kelly as modified by Choi comprises addition of an agent, namely enzyme produced by the bacteria as disclosed by Kelly. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93.

With respect to **claim 105:** The method of Kelly further comprises the step of contacting a swab with an agent, namely Stuart Transport medium, considered herein to be a neutral diluent inasmuch as its final pH is 7.4±0.2 (see attached reference material for Stuart Transport Medium). However Kelly does not explicitly disclose a swab that comprises a gelatine-based sponge. Choi discloses gelatin-based sponges. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93.

With respect to **claim 106:** The method disclosed by Kelly further comprises culturing cells collected on a swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function. However Kelly does not explicitly disclose a swab that comprises a gelatine-based sponge. Choi discloses gelatin-based sponges. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93.

With respect to **claim 118:** The micro-organism disclosed by Kelly is bacteria.

With respect to **claim 119:** The mammalian cell disclosed by Kelly and picked up by the swab disclosed by Kelly is a cell from blood plasma, inasmuch as the surface that is swiped by the swab is a wound surface containing blood.

With respect to **claim 120:** The mammalian cell disclosed by Kelly is any of leukocytes, erythrocytes and thrombocytes since the swab picks up whole blood from the wound surface.

With respect to **claims 138:** The swab disclosed by Kelly is attached to a support, namely a handle. However Kelly does not explicitly disclose a swab that comprises a gelatine-based sponge. Choi discloses gelatin-based sponges. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93.

With respect to **claim 139**: The support disclosed by Kelly comprises wood.

With respect to **claim 140:** The support disclosed by Kelly is a handle.

With respect to **claim 161:** Kelly discloses the transfer of bacteria onto the swab, wherein bacteria exhibit enzymatic activity in a wound environment and on the swab, producing enzymes that digest gelatin. However Kelly does not explicitly disclose a gelatine-based sponge. Choi discloses gelatin-based sponges. The motivation to modify the method of Kelly such that the swab comprises a gelatine-based sponge as disclosed by Choi is stated *supra* with respect to claim 93. Thus, it is examiner's position that the transferring step disclosed by Kelly as modified by Choi necessarily includes digestion of said gelatin.

With respect to **claim 163:** The method of Kelly further comprises the step of contacting said swab with an agent, namely Stuart Transport medium, considered herein to be a neutral diluent inasmuch as its final pH is 7.4±0.2 (see attached reference material for Stuart Transport Medium).

With respect to **claim 164:** The method disclosed by Kelly further comprises culturing cells collected on the swab in a growth medium inasmuch as Kelly discloses an operative swab culture, wherein a culture by its nature requires a growth medium to perform its intended function.

7. Claims 100 and 160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Choi, as applied to claim 93 or 97 above, and further in view of Lea et al (U.S. Patent Application Publication No. 2002/0019062)

With respect to **claim 100:** Kelly does not disclose that the target is an organic molecule. Choi does not remedy this deficiency. However, the use of swabs to swipe surfaces for organic molecules such as proteins are well known in the art as supported by Lea et al ('062, ¶¶0014,0117) Therefore, it would be obvious to one of ordinary skill in the art to modify the method of Kelly as modified by Choi such that the target is a protein as disclosed by Lea with a reasonable expectation of success to provide a means for diagnostic testing of said protein.

With respect to **claim 160:** Kelly does not explicitly disclose a pre-wetted swab. Choi does not remedy this deficiency. However, collecting samples with pre-wetted swabs is well-known in the art as supported by Lea (U.S. Patent Application Publication No. 2002/0019062, ¶0117) as swabs are often wetted with a buffer solution or other collection enhancing composition to ease the collection and separation of sample cells from the swab for transport and diagnostics. Therefore it would be obvious to one of ordinary skill in the art to modify the method of Kelly as modified by Choi such that the swab is pre-wetted as disclosed by Lea with a reasonable expectation of success to facilitate acquisition of target material from the wound.

8. Claims 102 and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of Choi, as applied to claim 93 or 97 above, and further in view of Laskey et al (U.S. Patent No. 6,303,323).

With respect to **claim 102:** Kelly does not explicitly disclose that the transferring step includes the washing of said target from the swab. Choi does not remedy this deficiency. Laskey disclose a method of antigen retrieval from a sample, wherein, in the process of transferring the sample for antibody staining, a washing buffer is used. Laskey discloses that the antigen retrieval

process is known in the art. Since the method of Laskey seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the method of Kelly as modified by Choi such that the transferring step includes washing of the target from the swab as disclosed by Laskey with a reasonable expectation of success to ensure all of the target material is available for testing and diagnosis.

With respect to **claim 162:** Kelly does not explicitly disclose that the transferring step includes the washing of said target from the swab. Laskey disclose a method of antigen retrieval from a sample, wherein, in the process of transferring the sample for antibody staining, a washing buffer is used. Laskey discloses that the antigen retrieval process is known in the art. Since the method of Laskey seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one of ordinary skill in the art to modify the method of Kelly as modified by Choi such that the transferring step includes washing of the target from the swab as disclosed by Laskey with a reasonable expectation of success to ensure all of the target material is available for testing and diagnosis.

9. Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly in view of in view of Choi, as applied to claim 93 above, and further in view of Ranjane et al (JP 09-296004 A (Derwent Abstract only)).

With respect to **claim 104:** Kelly does not disclose that the method further comprises extraction of the target by membrane filtration. Ranjane discloses extraction of bacterial cells from a sample via membrane filtration. Since the method of Ranjane seeks to solve a similar problem in the art to that with which applicant is concerned and discloses extraction of the bacteria for

further investigation and synthesis, it would be obvious to one of ordinary skill in the art to modify the method of Kelly such that the method further comprises the step of extraction of the target by membrane filtration to allow portions of the target to be set aside for further analysis and/or synthesis.

Allowable Claims

10. Claims 95, 141 and 158 are allowed.

Reasons for Allowance

11. The following is an examiner's statement of reasons for allowance:

a. With respect to claim 95, Kelly does not disclose or suggest a swab that comprises a gelatin-based sponge. Choi discloses a gelatin-based sponge, however the Kelly reference in combination with te Choi reference does not meet the limitations of the claim regarding the step of swiping a pre-wetted gelatine-based sponge over a target area followed by swiping a second dry gelatine based sponge. A further search revealed U.S. Patent No. 6,218,176 to Berthold et al, which discloses the step of swiping a prewetted swab over a target area surface then swiping a dry control swab over the same surface. However neither of these swabs comprises a gelatine-based sponge. Therefore even if one of ordinary skill in the art were to combine the teachings of Kelly and Choi and Berthold, the claimed method would still not be produced.

b. Similarly, with respect to claim 141, the combination of Kelly and Choi, alone or in combination with Berthold, would not meet the limitations regarding the wet-sampling

and dry-sampling steps with first and second devices according to claim 1. Claim 158 depends from claim 141 and is thus also allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

12. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 13, 2009 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,218,176. The reasons why Berthold does or does not disclose or suggest the claimed method is stated *supra* in the "Reasons for Allowance" section of this action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761